UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,950	08/18/1999	TOMMY EKSTROM	06275/188001	4952

26161 7590 12/04/2007

FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
KIM, JENNIFER M	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
12/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/367,950	EKSTROM, TOMMY	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/21/2007 & 8/28/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-36,38,42 and 43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-36,38,42 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the Board Decision rendered on August 28, 2007, PROSECUTION IS HEREBY REOPENED.

In view of the Board Decision made on August 28, 2007 the rejection of claims 13, 35, 36 and 42 under enablement provision of 35 U.S.C. 112, first paragraph, is hereby expressly **withdrawn**.

However, the rejection of Claims 13-15, 17, 18, 20-36, 38, 42 and 43 under 35 U.S.C. 103(a) as being unpatentable over Carling of record; and the rejection of claim 16 and 19 under 35 U.S.C. 103(a) as being unpatentable over Carling et al. of record as applied to claims 13-15, 17, 18, 20-36, 38, 42 and 43 above, and further in view of Aberg et al. (U.S.Patent 5,795,564) and Ryrfeldt et al. are being **maintained** for the reasons stated in the Examiner's Answer.

The Board has suggested the Examiner to consider **written descriptive support** for the phrases "instructing patient to inhale" and "instructing a patient to inhale the composition on demand", and in the event that the Examiner determines that the instant specification provides adequate written descriptive support for the phrases, to explain how these **phrases are to be interpreted**.

The Board has also suggested the Examiner to clearly explain whether the claims constitutes a **statutory process** by what subject matter the claimed process is transforming or reducing into a different state or thing.

In view of the above following additional rejections have been made:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-36, 38, 42 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The phrases **"instructing patient to inhale"** and **"instructing a patient to inhale the composition on demand"** lack literal support in the specification as originally filed.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. In this case, Applicants has not conveyed possession of the invention with reasonable clarity to one skilled in the art. Claim 13

recites the phrases **"instructing patient to inhale"** and **"instructing a patient to inhale the composition on demand"**. Claims are read in light of the Specification and although the phrases of a claim may appear to be definite, inconsistency with the specification disclosure or prior art teachings may make an otherwise definite claim take on an unreasonable degree of uncertainty. In this case, Applicants' equating term **"demand" by patient** with **"as needed"** recited in the specification on page 4, lines 4-5, lines 12-14, and Examples 5 and 6. However, this is a new matter because the term "demand" by patient is broader than the term "as needed" by patient.

The term "demand" described by Applicants encompasses not only the medical "need" determined by the patient but reads on the circumstances where there is **no "need"** of administration of the claimed composition (Oral Hearing Transcript 7:11-19). Applicants describe "demand" can include "zero" administration. (Oral hearing Transcript 4:3-8). There is no support for the "zero" administration in the specification as filed. Therefore, there is lack of written description of the broad limitation of "demand" as instantly claimed.

Further, the phrase **"instructing patient to inhale"** is not described in such a way that Applicants' have possession of such phrase. This instant specification does not provide a basis for **"instruct a patient to inhale".** There is no literal support. It is noted that Applicants states that instruct a patient to inhale can be performed by any number of routes, including printed matter (e.g. a product insert accompanying an inhaler, video) (Oral Hearing Transcript 2:21-24 and 3:6-10)). None of these instructions are described in the instant specification.

This specification provides administration of the claimed combination is useful for the treatment of asthma, but it does not describe additional step of "instructing" the patient to inhale the composition which may be **a next step**. Given the lack of a basis provided by instant specification that is necessary and critical element of the instant invention (see oral hearing Transcript 4:11-13), one of skill in the art would **not have been able to envision that critical element of "instructing a patient to inhale"** is sufficiently described in the specification. Therefore, one of skill in the art would reasonably have concluded Applicants were **not** in possession of the claimed invention of what is considered as a **next additional step** beyond what is originally described in the instant specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13-36, 38, 42 and 43 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 13 requires only one positive step-instructs a patient to inhale a composition on demand. It is noted that a process is an act or a series of acts,

performed upon the subject matter to be transformed and reduced to a different state or thing.

According to Applicants, this step of instructing a patient can be performed by any number of routes, including printed matter (e.g. a product insert accompanying an inhaler). Therefore, this claim **is directed to the manipulation of an abstract idea (e.g. the communication of a concept) without any requirement that a practical application actually be associated with this abstract idea.**

Neither transformation nor reduction would result from the claimed invention because whether the patient actually performs the administration of the claimed composition is not an element of the claim. (see Oral Hearing Transcript 11:4-8). The actual "reduction" or "transformation" would only take place with an actual administration of the claimed combination. In this case, there is no reduction or transformation would take place with the claimed invention because the claims do not recite necessary step of a practical application associated with this abstracted idea.

Therefore, the claimed subject matter is deemed non-statutory.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 13-15, 17, 18, 20-36, 38, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling of record.

Carling et al. on page 6, lines 5-30, teach the suitable daily asthmatic dose of formoterol fumarate dihydrate as required by claim 15 and budesonide within Applicant's daily dosage of "on demand" (twice a day) and the dosages strongly depends on the patient (age, weight etc.), severity of disease (mild, moderate, severe asthma etc..).

Carling et al. on pages 7-9 exemplify amounts of active agents per dose of inhalation, which calculate up to 8 inhalation per day without going over the maximum daily dosage.

Carling teaches at page 8-14, page 3, line 35 through page 4, line 10, lines 30-35, page 6, lines 5-30, and page 7, lines 1-5, teach a composition comprising Applicant's active agents use for treating respiratory disorder such as asthma set forth in claims 13-15, 17-18, 20-21, and 23.

Carling et al. at page 4, lines 3-10, also teach that the combination of formoterol and budesonide has not only a greater efficiency and duration of bronchodilator action but also a rapid onset of action.

The difference between Carling et al. and Applicant's invention is instructing a patient to inhale, on demand, as determined by the patient based on the patient's

symptoms, to provide short-term symptomatic relief of acute asthmatic symptoms set forth in claims 13 and 36, instructing patient to inhale additional doses as needed if he experiences asthma including acute asthmatic episode, a specific carrier set forth in claim 24, the molar ratio of active agents set forth in claim 14, and the particle size set forth in claim 22.

However, to instruct the patient to inhale, on demand, as determined by the patient's symptoms in acute asthmatic episode is obvious since Carling et al. teach that the dosages strongly depends on the severity of disease (mild, moderate, severe asthma) and the suitable daily dosage is up to 8 inhalation. One of ordinary skill in the art would be motivated to instruct those patient with severe asthma or acute asthmatic attack to use the Carling's composition as needed bases up to 8 inhalations as suggested by Carling et al. that the dosages strongly depends on the severity of disease and to achieve maximum benefit of daily dosage recommended by Carling et al. It is noted that combination of formoterol with budesonide is well known to be beneficial for the treatment of asthma as taught by Carling et al. Moreover, if that patient experiencing acute asthmatic attack even with ongoing twice a day dosing regimen, he still can safely inhale additional 6 inhalations without going over the maximum suitable daily dosage in general asthmatic condition taught by Carling et al. to achieve its known therapeutic relief from asthmatic attack. The skilled artisan would have been motivated to instruct the patient to use Carling's composition as needed bases up to 8 inhalations a day with reasonable expectation of successfully achieving maximum benefit in treatment of any severity condition of asthma in general including

acute asthmatic condition. **Further, patients disclosed by Carlings who is conventionally as taught by Carlings, e.g. two-times per day to prevent and treat asthma symptoms would be included in the range of "demand" because those patients may only "need" twice a day dosing per their medical condition.**

The molar ratio of active agents to be used set forth in claim 14, the selection of carrier set forth in claims 23 and 24, and the particle size of active agents set forth in claim 22, are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations.

Claim 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling et al. of record as applied to claims 13-15, 17, 18, 20-36, 38, 42 and 43 above, and further in view of Aberg et al. (U.S.Patent 5,795,564) and Ryrfeldt et al. of record.

Carling et al. as applied as before.

Carling et al. do teach the isomer of formoterol set forth in claim 16 and the specified epimer of budesonide set forth in claim 19.

Aberg et al. teach (R, R) isomer of formoterol as required by claim 16 is a potent bronchodilator with reduced adverse effects in treatment of asthma. (abstract, column, 1, lines 25-35).

Ryrfeldt et al. teach that 22R epimer of budesonide is more potent in the treatment of bronchial asthma than 22S epimer.

However, it would have been obvious to one of ordinary skill in the art to employ (R, R) enantiomer of formoterol and 22 R epimer of budesonide in view of Aberg et al. and Ryrfeldt et al. because both of the references of Aberg and Ryrfeldt teach specific

isomers form that possesses potent asthmatic effect of the active agents utilized in Carling reduced adverse effects in treatment of asthma. One would have been motivated to employ (R,R) isomer of formoterol and 22R epimer of budesonide in Carling's composition with reasonable expectation of successfully treating asthmatic patients with reduced adverse effects.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Response to Applicants' Interview Summary

Applicants' interview summary filed November 21, 2007 have been fully considered. Applicants proposed amending the preambles of independent claims 13, 35, 36 and 42 to be directed to "prevention **OR** treatment" instead of "prevention **AND** treatment". The Examiner do not agree with the proposal because the decision made by the board was based on "prevention AND treatment" not based on more broad

claims drawn to "prevention OR treatment" as proposed. Therefore, the proposed claim language would broaden the scope of the claims.

With respect to Written Description, Applicants argue that the concept of instructing the patient is embedded in the entire disclosure such that the reader would certainly understand it to be there. Applicants further argue that the phrase is derived from (a) nature of the invention and (b) what is made explicit in the specification. As to the Nature of the invention, Applicants state that the combination therapy described in the claims includes formoterol and budesonide is a prescription medicine, and therefore, it will be prescribed (as for any prescription medicine) with some sort of instructions regarding a dosage and a frequency. Thus, the doctor has to instruct the patient in how much to use and when and that without such an instruction, the patient would have no idea what to do with the drug. It is inconceivable that an inhaler containing a potent drug would be given to the patient with no instructions whatsoever. To this response it is the Examiner's position that there is no literal support for the phrase "instructing the patient" in the specification as originally filed and, therefore, it constitutes new Matter. While the Examiner acknowledges that instruction is necessary while prescribing a drug to a patient, however, it is next additional step beyond what is described in the specification. There is no written description of additional concept of instructing the patient in the instant specification as filed.

As to the b) explicit language, Applicants state that the specification at page 4, lines 4-5, states that "in the present invention, it has been found that it is possible for the

patient to administer this mixture as often as needed." Applicants state that it is understood that the patient would receive instruction from some source to self-administer the mixture "as needed" as it would be unreasonable to assume that the patient could decide this on his own for a potentially dangerous drug. This is not found persuasive because one of ordinary skill in the art upon the reading of the disclosure in the specification at page 4, lines 4-5 above, would reasonably recognized that the Applicants had **possession of the administration of the combination as often as needed,** but **would not reasonably convey that Applicants had possession of additional step of instructing the patient.**

Applicants argue that the specification page 4, lines 19-23, states that " a treatment for patients suffering from respiratory disease, particularly asthma (including allergic conditions, e.g., episodic or intermittent asthma), will therefore be to use the combination formoterol/budesonide for maintenance therapy as well as on an as needed basis (or rescue purpose), e.g., for prevention of exercise and/or allergen induced asthma" and that this passage conveys that it is up to the patient to decide when the drug is needed, and it is obvious that the details of this treatment would have to be communicated to the person who is self-administering the treatment, i.e. the patient. This is not persuasive because one of ordinary skill in the art would recognized that the passage only conveys that treatment of asthma is useful as needed basis. It does not state what may be the next step of instructing the patient.

Applicants points out Examples 5 at page 8 of use " as needed"; Example 6 at page 9 sates "as sole medication to be taken as needed until the asthma resolves..."; page 1-2 says, "too complicated therapy...may lead to misunderstanding and communication problems between patient and doctor..."; page 2, line 1-2 states "compliance", all of these are examples that imply instructions. This is not found persuasive because none of the statements equate or are synonymous with the term "instruction". Applicants argue that the treatment regimens and patients and recommended daily doses is description that **inherently** requires a source of instruction that will teach the patient how to self-administer the combination therapy. This is not found persuasive because there is series of steps of involving a discovery of the drug to advertising or to place the drug on a market. In this case, there is lack of written description of the additional step of instructing a patient. It is the Examiner's position that there is a disclosure of claimed combination for the treatment of asthma as needed bases but there is no disclosure of next step involving instructing the patient. Therefore, the instruction is not inherent from the drug discovery but it is next additional step.

Applicants states that the in the conclusion of the interview, the Examiner seemed to be in agreement that the claims were supported by adequate written description and intent to discuss the issues with her supervisor. The Examiner has communicated with her supervisor and it was decided that the phrases at issue lack written description as originally filed for the reasons given above.

As to the Claim interpretation, the Examiner determines that there is lack of written description. Currently, the claims are drawn to "on demand" which is broader than what is disclosed in the specification (i.e. "as needed") because Applicants' states that the "on demand" **can be zero times in one day**. There is no support in the specification that the administration of "zero". Therefore, the claims are interpreted as broader than what is actually disclosed in the specification, "as needed".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Primary Examiner
Art Unit 1617

Jmk
November 29, 2007